December 13, 2017

Hon. Claire C. Cecchi, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King, Jr. Bldg. & U.S. Courthouse
Courtroom MLK 5B
50 Walnut Street
Newark, New Jersey 07101

Re: Proton-Pump Inhibitor Products Liability Litigation (No. II); 2:17-md-2789 (CCC)(MF) (MDL 2789)
Defendants' Proposal Regarding Master Complaint, Master Answers, Short-Form Adoption By Reference Complaints, Short-Form Adoption By Reference Answers, and Direct Filing Order

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Dear Judge Cecchi:

Pursuant to this Court's November 16 Order, Defendants respectfully submit the following letter brief in support of Proposed Case Management Order ("CMO") No. __ (Master Complaint, Master Answers, Short-Form Adoption By Reference Complaints, Short-Form Adoption By Reference Answers, and Direct Filing) (a "Direct Filing Order"). A copy of the Proposed Direct Filing Order, highlighting the competing provisions, is attached as Exhibit A.[1]

I. Introduction

We are pleased to report to the Court that the parties have exchanged revised drafts of a proposed Direct Filing Order and have been able to narrow some of the disputed issues since our last status conference. The proposed order also includes a framework for Master Pleadings -- including a Master Complaint, Master Answer, Short-Form Complaint and Short-Form Answer. Although we have made strides in narrowing previously disputed issues, there remain fundamental issues that divide the parties.

As more fully set forth in the Defendants' November 6, 2017 letter ("Defendants' November 6 Letter") (Doc. 67), a direct filing order implicates substantial constitutional, statutory and procedural rights of defendants, including personal jurisdiction and venue rights, and thus necessitates defendants' consent. *See In re Kaba Simplex Locks Mktg. & Sales Practices Litig.*, No. 1:11-MD-2220, at *6 (N.D.

[1] In this letter, the Section citations refer to the Sections as proposed by Defendants.

Ohio Aug. 1, 2012) (Exhibit B); *see also In re Heartland Payment Systems, Inc. Consumer Sec. Data Breach Litig*., 2011 WL 1232352 (S.D. Tex. Mar. 31, 2011) (granting motion to dismiss directly filed action in MDL for lack of personal jurisdiction); *In re Depuy Orthopaedics*, 870 F.3d 345, 358 (5th Cir. 2017) (Jones, J., concurring in part, dissenting in part) (noting that the "district court lacked jurisdiction over these direct-filing plaintiffs' cases, as our panel majority concludes"; Judge Jones would have granted mandamus).

Moreover, direct filing orders bypass the ordinary role of the Judicial Panel on Multidistrict Litigation ("JPML") in assessing whether cases should be included in, and when they should exit, an MDL proceeding. Defendants acknowledge that direct filing orders have been adopted (with defendants' consent) in some MDL proceedings and appreciate certain salutary benefits such orders potentially provide at the front end of the litigation for the Court and the plaintiffs. Indeed, these orders predominantly benefit plaintiffs' counsel who can file all of their actions in a single MDL court, without the need to retain local counsel or otherwise gain admission to local courts to file. However, these conveniences to plaintiffs may lead to a proliferation in the number of filings without a sufficient filter as to their basic merits or for the naming of particular defendants. Thus, this risk heightens the general concern noted by Judge Land that "MDL consolidation for products liability actions does have the unintended consequence of producing more new case filings of marginal merit in federal court, many of which would not have been filed otherwise." *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig*., No. 4:08-MD-2004 (CDL), 2016 WL 4705827, at *2 (M.D. Ga. Sept. 7, 2016).

Moreover, at the back end of the litigation, direct filings can add substantially to the burdens of the MDL court, and defendants, when the pretrial work has reached the point where the cases need to be transferred to the appropriate federal courts for further proceedings and trials. Ordinarily, an MDL will reach a stage where the MDL court will make a suggestion of remand of cases to the JPML. If the JPML concurs that remand is appropriate, it will simply send the actions back to the federal districts where they originated. However, with respect to actions directly filed in an MDL, the MDL court will need to make an individual determination for each such directly filed action as to the district where the case should be sent for further proceedings and trials. And the burdens of identifying and potentially moving on each and every case where plaintiffs are proposing transfer to an improper venue or one which lacks personal jurisdiction will primarily fall upon defendants. If there is no direct filing order, cases simply go back to where they were originally filed and this whole exercise is avoided.

A fundamental issue dividing the parties is the import of product identification and proof of injury to the direct filing process to avoid inundating the Court with cases that ultimately may be dismissed for lack of product use or qualifying injury. As set forth below, Defendants' position is that their constitutional and statutory rights must be preserved, particularly for direct filings by out-of-state Plaintiffs, and, further, that direct filed cases must have a substantiated basis to be filed in this MDL proceeding against the named Defendants for alleged kidney injuries subsequent to use of the named Defendants' PPI products. In addition, there are a few other terms which Defendants seek. These additional terms will further assist in calibrating an equitable and reasonable balance between the efficiencies of a Direct Filing Order and the challenges that may be presented by the influx of cases filed by Plaintiffs from around the country, in a forum (the District of New Jersey) which otherwise lacks personal jurisdiction over the Defendants and would otherwise be an improper venue.

II. Limited Product Identification Records and Qualifying Kidney Injury Records (Section III(C))

For the reasons set forth in Defendants' Request for Entry of Proposed CMO No. ___ (Plaintiff Fact Sheet, Product Identification Records, and Qualifying Kidney Injury Records), submitted today, and Defendants' prior submissions, Plaintiffs should be required to disclose (1) appropriate record(s) substantiating product identification/ingestion of a specific PPI product(s) and the naming of the implicated defendants; and (2) appropriate record(s) substantiating diagnosis of the alleged subsequent kidney-related injury. As set forth in Defendants' proposed Direct Filing Order, direct filed cases should be subject to the product identification and proof of injury CMO with the proposed language submitted by Defendants. The issue of product identification and proof of injury is of exceedingly significant import in this MDL proceeding consisting of many defendants and many particular products. Resolution of the vital threshold question as to what documentation should be deemed sufficient is necessary *before* Defendants can decide whether to consent to a Direct Filing Order.

III. Remaining Disputed Terms for Resolution

A. Contents of Short-Form Complaints (Section II(C))

The proposed Direct Filing Order includes provisions relating to Short-Form Complaints (whether or not the actions are directly filed in the MDL). Although the parties have agreed to much of the contents of those complaints, Defendants assert that Plaintiffs should be required to identify:

- ***3. The date(s) that the PPI user used any PPI product;***
- 6. The ***type of kidney-related*** injury and a statement of damages for which a claim is asserted;
- **7.** The approximate date that Plaintiff or PPI User ***first experienced the kidney-related injury*** for which a claim is asserted (the injury identified in paragraph 6 above);
  - ***a. The city and state in which the Plaintiff or PPI user resided at the time of such injury;***

Axiomatically, there should be no burden for a plaintiff suing in tort to identify what his/her injury is and where and when that injury occurred. Nevertheless, the PSC resists including in a Short-Form Complaint the "type of kidney-related" injury, the state where Plaintiff allegedly experienced that injury, and any information relating to the date of PPI use (*i.e*., the bolded terms above). The JPML created this MDL for actions arising from certain kidney injuries. At a minimum, Plaintiffs should know, and should provide, the type of kidney injury. The location where Plaintiff resided at that time is relevant to the timeliness of the claims (among other issues, such as specific jurisdiction and proper venue) and should be readily and easily available for Plaintiffs to provide. In the *Testosterone Replacement Therapy* MDL proceeding, plaintiffs are required to provide in their Short-Form Complaint the date of any alleged PPI use, the alleged injury, the approximate date of the injury and where plaintiff resided at the time. *See* Master Short-Form Complaint For Individual Claims ¶¶ 8, 9, 14, 15, *In re Testosterone Replacement Prods. Liab. Litig.*, MDL No. 2545, 1:14-cv-01748 (N.D. Ill.) (No. 777-1) (Exhibit C). Even if some information is later provided in a Plaintiff Fact Sheet, which is months away and the form of which is the subject of dispute, this basic preliminary, readily available information should be provided in the Short-Form Complaint.

B. Application to Previously Filed (or Rem7oved) Actions (Sections II(B) & III(B))

Defendants' proposed Direct Filing Order clarifies that the Order applies to both newly filed and previously filed actions. For efficiency and consistency, the Short-Form pleadings (both complaints and answers) should apply to all actions so that they are uniform. *See* Pretrial Order No. 3 on Master Pleadings at 4, *In re Fluoroquinolone Prods. Liab. Litig.*, MDL No. 15-2642 (JRT) (D. Minn. Mar. 1, 2016) (No. 19) ("Any Plaintiff with a case currently pending in these MDL proceedings as of the date of the filing of the Master Complaint must file a Short Form Complaint . . .") (Exhibit D). Moreover, in this MDL proceeding, many actions have already been directly filed in this district by out-of-state Plaintiffs,

prematurely, without the consent of Defendants and without any order permitting those filings. If the direct filing provisions do not apply to previously filed actions – including, *inter alia*, preserving personal jurisdiction, venue and *Lexecon*, as well as addressing choice of law, pleading and transfer issues – Defendants will have no choice but to move to dismiss those cases for lack of personal jurisdiction (with the exception of the forty-five cases in which the AstraZeneca Defendants have agreed to waive their right to assert a lack of personal jurisdiction). In the alternative, the parties will need to negotiate and submit yet another CMO detailing all of the same issues, but as they relate to previously filed actions.

C. Right to File Motions to Dismiss or Motions for Judgment on the Pleadings (Section III(H))

Under the Federal Rules of Civil Procedure ("FRCP"), a defendant may move to dismiss a complaint (or move for judgment on the pleadings) as of right. *See* FRCP 12. The fact that these cases are part of an MDL does not and should not abridge Defendants' rights. Defendants would agree to entry of a Direct Filing Order only to the extent it allows for such motion practice as a matter of right, without requiring leave of Court before filing each such motion. This is particularly important if Defendants do not obtain adequate product identification or proof of injury. Allowing Defendants to move, as permitted under the FRCP, will serve as a check on pleadings which do not adequately make their allegations against Defendants.

In their November 6 submission, the PSC interprets CMO No. 3 as precluding Defendants from moving to dismiss or moving for judgment on the pleadings absent leave of Court. In CMO No. 3, the Court ordered that "Defendants' pending Motions to Dismiss are hereby administratively terminated with a right to reinstate at a later date. The parties shall meet and confer regarding the appropriate time to bring such motions." The Order did not rescind Defendants' rights to file motions under FRCP 12, but simply "administratively terminated" pending motions filed prior to the creation of the MDL while the parties negotiated the foundational orders for this MDL proceeding.

IV. Mechanism to Transfer Directly Filed Cases Out of the MDL (Section III(F))

Nothing in the MDL statute (28 U.S.C. § 1407) permits or provides for a direct filing order, which would effectively allow plaintiffs to skip and bypass the JPML transfer process. Further, there is no "transferor court" to which the JPML could remand a directly filed case after MDL proceedings. *See* Defendants' November 6 Letter. To

remedy that infirmity and as other MDL courts have done, if Defendants provide their consent and a Direct Filing Order is utilized, the mechanism for transfer of a direct filed action out of the MDL proceeding should be 28 U.S.C. § 1404 (convenient forum), rather than "remand" under 28 U.S.C. § 1407 (the MDL statute). The new proposed Direct Filing Order makes conforming changes throughout.[2]

V. Conclusion

For the reasons set forth above and in their November 6 Letter, Defendants respectfully request that the Court adopt their proposed reasonable terms for a Direct Filing Order. If the terms are adopted, Defendants will consent to the entry of the Direct Filing Order. We look forward to the December 18 Conference with the Court.

Respectfully submitted,

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[2] The proposed Direct Filing Order retains references to "remand" only with respect to preserving the right to seek remand or a suggestion of remand in this MDL proceeding (with respect to actions not directly filed in this Court) as so ordered by the Court or as otherwise permitted by law. *See* Section III(E)(4) ("Nothing herein shall preclude any party from moving for remand or a suggestion of remand, or otherwise seeking transfer under 28 U.S.C. § 1404, at any time as ordered by the Court or as otherwise permitted by law.").

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